**IN THE UNITED STATES DISTRICT COURT**
**FOR THE NORTHERN DISTRICT OF ILLINOIS**
**EASTERN DIVISION**

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| **FEDERAL TRADE COMMISSION, STATE OF ILLINOIS, and STATE OF MINNESOTA** | ) | |
| **Plaintiffs,** | ) | **No. 25-cv-2391** |
| **v.** | ) | **Judge Jeffrey I. Cummings** |
| **GTCR, LLC, GTCR BC HOLDINGS, LLC, and SURMODICS, INC.** | ) | |
| **Defendants.** | ) | |

**ORDER**

Plaintiffs Federal Trade Commission, State of Illinois, and State of Minnesota bring this case against defendants GTCR, LLC, GCTR BC Holdings, LLC ("BC Holdings"), and Surmodics, Inc. ("Surmodics"), seeking to enjoin a proposed merger between BC Holdings and Surmodics.

BC Holdings served the United States Food and Drug Administration ("FDA"), a non-party, with a subpoena *duces tecum* (the "Subpoena") that seeks all Premarket Approval, De Novo, and 510(k) submissions received by the FDA from January 1, 2010 to the present for certain medical devices that may use a lubricious coating. Before the Court is BC Holdings' motion to compel the FDA to comply with the Subpoena. For the reasons set forth before, BC Holdings' motion, (Dckt. #154), is denied.[1]

[1] The FDA suggests, in a footnote, that this Court does not have jurisdiction to resolve this motion and that "GTCR should have filed its motion to compel in the district where compliance is required, the District of Maryland or the District of Columbia." (Dckt. #164 at 2, fn. 2). BC Holdings asserts that this Court has jurisdiction under the Clayton Act. Pursuant to 15 U.S.C. §23, in antitrust actions brought by or on behalf of the United States, "subpoenas for witnesses who are required to attend a court of the United States in any judicial district in any case, civil or criminal, arising under the antitrust laws may run into any other district." Other courts have found that 15 U.S.C. §23 implicitly confers nationwide enforcement power. *See United States v. Anthem, Inc.*, No. CV 16-1493 (ABJ), 2016 WL 11164033, at *1 n.1 (D.D.C. Dec. 7, 2016); *see also Fed. Trade Comm'n v. Kroger Co.*, No. 3:24-CV-00347-AN, 2024 WL 3400098 (D.Or. July 12, 2024); *Fed. Trade Comm'n v. Meta Platforms, Inc.*, No. CV 20-3590 (JEB), 2025 WL 985530 (D.D.C. Apr. 2, 2025). The Court is convinced by the analyses in *Anthem*, *Kroger*, and *Meta Platforms* that 15 U.S.C. §23 confers nationwide enforcement power. The Court, accordingly, finds that it has jurisdiction to hear the present motion to compel.

## I. LEGAL STANDARD

Federal Rule of Civil Procedure 45 permits a party to issue a subpoena directing a non-party to "produce designated documents, electronically stored information, or tangible things in that person's possession." Fed.R.Civ.P. 45(a)(1)(A)(iii). The ability to use subpoenas to obtain information from non-parties is not unlimited, however; Rule 45 provides that the issuer of "a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena." Fed.R.Civ.P. 45(d)(1). Rule 45 also instructs courts that they "must protect" non-parties "from significant expense resulting from compliance" with a subpoena. Fed.R.Civ.P. 45(d)(2)(B)(i)&(ii).

Consequently, "the court should be particularly sensitive when weighing the probative value of the information sought against the burden of production on the non-party." *Martin v. United States*, No. 13-CV-3130, 2015 WL 7783516, at *2 (C.D.Ill. Dec. 3, 2015) (cleaned up). Indeed, "[i]n keeping with the text and purpose of Rule 45(c)(3)(A), it has been consistently held that 'non-party status' is a significant factor to be considered in determining whether the burden imposed by a subpoena is undue." *United States ex rel. Tyson v. Amerigroup Illinois, Inc.*, No. 02-C-6074, 2005 WL 3111972, at *4 (N.D.Ill. Oct. 21, 2005); *Parker v. Four Seasons Hotels, Ltd.*, 291 F.R.D. 181, 188 (N.D.Ill. 2013) (same). "Non-parties are afforded this consideration because they have a different set of expectations than parties. . . . While parties to a lawsuit must accept the invasive nature of discovery, non-parties experience an unwanted burden." *HTG Capital Partners, LLC v. Doe(s)*, No. 15-C-2129, 2015 WL 5611333, at *3 (N.D.Ill. Sept. 22, 2015) (cleaned up).

In addition to the non-party status of the subpoenaed entity, courts consider a number of other factors when determining if the burden imposed by a subpoena is "undue." These factors include whether: (1) the information requested is relevant; (2) the party requesting the information has a substantial need for the documents; (3) the document request is overly broad; (4) the time period the request covers is reasonable; (5) the request is sufficiently particular; and (6) whether compliance with the request would, in fact, impose a burden on the subpoenaed party. *Am. Soc. of Media Photographers, Inc. v. Google, Inc.*, No. 13 C 408, 2013 WL 1883204, at *2 (N.D.Ill. May 6, 2013) (citing to *Northwestern Memorial Hospital v. Ashcroft*, 362 F.3d 923, 927 (7th Cir. 2004)).

## II. DISCUSSION

BC Holdings moves to compel the FDA to comply with the Subpoena and produce medical device approval applications filed from January 2010 to the present for devices that may use a lubricious coating within any product codes listed in Appendix A to the Subpoena. Among other things, the FDA argues that compliance with the Subpoena would require it to disregard its *Touhy* regulations and otherwise impose an undue burden. The Court agrees and addresses both arguments below.

*Touhy* regulations are developed by federal agencies to provide a method for determining whether and how to respond to subpoenas or other requests for information. *See St. Vincent Medical Group, Inc. v. United States Department of Justice*, 71 F.4th 1073, 1074 (7th Cir. 2023);

*see also United States ex rel. Touhy v. Ragen*, 340 U.S. 462 (1951). The FDA's *Touhy* regulations are set forth at 21 C.F.R. Part 20, and provide in relevant part that a subpoena *duces tecum* shall comply with rules governing public disclosure established in subpart D. In turn, Subpart D to Part 20 prohibits disclosure of trade secret information, commercial confidential information, and personally identifiable information. 21 C.F.R. §§20.61(c), 20.63(a). To prevent disclosure of this material, FDA staff are required to identify and complete page-by-page, line-by-line reviews of any requested document to redact such exempt information. (Dckt. #164 at 36). The FDA estimates that the Subpoena would require it to review an estimated 350 million pages of material, requiring an estimated seven million agency hours. (*Id.* at 5). Even narrowing the universe to only the product codes listed in Appendix A of the Subpoena, the FDA still estimates approximately 400,000 hours of work. (*Id.* at 6).

For its part, BC Holdings argues that the documents produced by FDA need not be redacted because the protective order previously entered obviates any confidentiality concerns. (Dckt. #154 at 10–11). Not so.

BC Holdings cites to *Methodist Health Servs. Corp. v. OSF Healthcare Sys.*, No. 14 CV 7748, 2014 WL 5465401, at *2 (N.D.Ill. Oct. 27, 2014) and *Meridian Labs., Inc. v. Oncogenerix USA, Inc.*, No. 18 CV 6007, 2021 WL 4768256, at *4 (N.D.Ill. 2021) to support its argument that courts routinely compel non-party subpoena recipients to produce relevant materials when a protective order would protect the confidentiality of those materials. But neither *Methodist* nor *Meridian Labs*. involve non-parties that were subject to *Touhy* regulations.

BC Holdings also cites *Buergofol GmbH v. Omega Liner Co., Inc.*, No. 4:22-CV-04112-KES, 2025 WL 859894 (D.S.D. Mar. 19, 2025), a non-binding case where the court found that the United States Customs and Border Protection's ("CBP") decision not to respond to a subpoena issued by defendant Omega after it reviewed the subpoena under the CBP's Touhy regulations was arbitrary and capricious. In *Omega*, the court rejected the CBP's argument that disclosure would violate the Trade Secrets Act and improperly reveal confidential commercial information without the owner's consent because the CBP failed to properly consider the existence and impact of the applicable protective order. *Id.* at *6–7.

However, the factual circumstances in *Omega* are different from those in this case. Here, the FDA has considered the protective order and argues it is still bound by its obligations under the Trade Secret Act, Food, Drug, & Cosmetic Act, and Freedom of Information Act. Furthermore, unlike in *Omega* (where the defendant sought "minimal data" that the CBP had already collected and maintained, 2025 WL 859894, at *8), the FDA argues—and indeed, has put forth sworn testimony—that completing its review under the FDA's *Touhy* regulations and responding to the Subpoena would be burdensome and take hundreds of thousands, if not millions, of hours. Even if the protective order obviated the need for redactions—and the Court does not find that it does—at a minimum, the FDA "staff would need to download each [of tens of thousands of] submission[s] from [their] respective storage application." (Dckt. #164 at 5). This would impose an undue burden. Thus, *Omega* is factually distinguishable.[2]

[2] The Court notes that it does not understand *Omega* to stand for the proposition that a federal agency can respond to a subpoena without first reviewing the subpoena under its *Touhy* regulations.

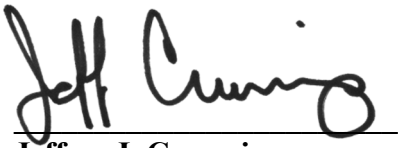
Finally, BC Holdings cites *Albany Molecular Rsch., Inc. v. Schloemer*, 274 F.R.D. 22 (D.D.C. 2011), which likewise does not support its argument. In *Schloemer*, the plaintiff issued a third-party subpoena to the FDA requesting *one* drug application as well as related documents. Nothing in *Schloemer* supports a finding that the FDA need not redact trade secret, confidential, and personally identifiable information in accordance with its *Touhy* regulations, or that the FDA should be compelled to expend hundreds, thousands, or millions of work hours to respond to the Subpoena.

Accordingly, BC Holdings fails to cite any precedent or persuasive authority to support its position that the existence of a protective order, in and of itself, permits the FDA to eschew its *Touhy* regulations and produce unredacted documents, particularly where the FDA has articulated a significant burden it must undertake to gather and produce such documents. Its motion to compel the FDA to comply with the Subpoena is therefore denied.

## CONCLUSION

For the reasons set forth above, the Opposed Motion of GTCR BC Holdings, LLC to Compel United States Food and Drug Administration to Comply with Subpoena, (Dckt. #154), is denied.

**DATE: July 16, 2025**



**Jeffrey I. Cummings**
**United States District Court Judge**